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Notice of Allowability

Application No.

10/630,445

Examiner

(Jackie) Tan-Uyen T. Ho

Applicant(s)

FERREE, BRET A.

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/16/07.
2. ☒ The allowed claim(s) is/are 85-91,93-106 and 108-113.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 3/19/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date herewith.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. The abstract filed on 7/30/03 is amended as follow:

Methods and apparatus for treating disc herniation provide a conformable device which assumes a first shape associated with insertion and a second shape or expanded shape to occlude the defect which typically follows partial discectomy. The device may take different forms ~~according to the invention~~, including patches size to cover the defect or plugs adapted to fill the defect. ~~In a preferred embodiment, however, the device is,~~ a gel or other liquid or semi-liquid which solidifies to occlude the defect from within the body of the disc itself. ~~In another preferred embodiment,~~ a mesh screen is collapsed into an elongated form for the purposes of insertion, thereby minimizing the size of the requisite incision while avoiding delicate surrounding nerves. Such a configuration also permits the use of instrumentation to install the device, including, for example, a hollow tube or sheath adapted to hold the collapsed screen, and a push rod to expel the collapsed device out of the sheath for use in occluding the disc defect. A device ~~according to the invention~~ may further include one or more anchors to assist in permanently affixing the device with respect to the defect.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with John Kappos on 4/12/07.

- Claim 85, line 8, after "the defect" insert – to prevent escape of nucleus pulposus through the defect--
- Claim 85, line 10, delete "the porous mesh prevents escape of nucleus pulposus through the defect,"
- Claim 99, line 8, after "the defect" insert – to prevent escape of nucleus pulposus through the defect--

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- Claim 99, line 10, delete "the porous mesh prevents escape of nucleus pulposus through the defect,"

Ray et al. (5,824,093) Krapiva (5,645,597) disclose a method of replacing nucleus and the implant including a porous mesh. However, Ray et al. do not disclose the method for treating an annulus fibrosis having a defect and the method comprising the steps of expanding the porous mesh or implant to a diameter larger than the defect to prevent escape of nucleus pulposus through the defect.

4. The following is an examiner's statement of reasons for allowance: claims 85-91, 93-106, 108-113 are allowed because the prior art fails to disclose or suggest a method for treating an annulus fibrosis comprising the steps as claim. Especially the step of expanding the porous mesh radially by reducing the length between the distal and proximal ends and advancing the implant distally beyond the outer layer wherein the proximal end of the porous mesh is located distally beyond the outer layer of the annulus fibrosis.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

April 12, 2007